and requested the appointment of a conference committee to consider the differences between the two houses; the House adopted the conference committee report on H.B. No. 743 on May 31, 2015: Yeas 143, Nays 1, 1 present, not voting; passed by the Senate, with amendments, on May 25, 2015: Yeas 27, Nays 4; at the request of the House, the Senate appointed a conference committee to consider the differences between the two houses; the Senate adopted the conference committee report on H.B. No. 743 on May 30, 2015: Yeas 27, Nays 4.

Approved June 19, 2015.

Effective June 19, 2015.

PRESCRIPTION AND PHARMACEUTICAL SUBSTITUTION OF BIOLOGICAL PRODUCTS; AMENDING PROVISIONS SUBJECT TO A CRIMINAL PENALTY

CHAPTER 1007

H.B. No. 751

AN ACT

relating to the prescription and pharmaceutical substitution of biological products; amending provisions subject to a criminal penalty.

Be it enacted by the Legislature of the State of Texas:

SECTION 1. Section 562.001, Occupations Code, is amended by amending Subdivision (1) and adding Subdivisions (1–a) and (1–b) to read as follows:

(1) *"Biological product" has the meaning assigned by Section 351, Public Health Service Act (42 U.S.C. Section 262).*

(1–a) "Generically equivalent" means a drug that is pharmaceutically equivalent and therapeutically equivalent to the drug prescribed.

(1–b) "Interchangeable," in reference to a biological product, has the meaning assigned by Section 351, Public Health Service Act (42 U.S.C. Section 262), or means a biological product that is designated as therapeutically equivalent to another product by the United States Food and Drug Administration in the most recent edition or supplement of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.

SECTION 2. Section 562.002, Occupations Code, is amended to read as follows:

Sec. 562.002. LEGISLATIVE INTENT. It is the intent of the legislature to save consumers money by allowing the substitution of lower-priced generically equivalent drug products for certain brand name drug products *and the substitution of interchangeable biological products for certain biological products* and for pharmacies and pharmacists to pass on the net benefit of the lower costs of the generically equivalent drug product *or interchangeable biological product* to the purchaser.

SECTION 3. Section 562.003, Occupations Code, is amended to read as follows:

Sec. 562.003. DISCLOSURE OF PRICE; PATIENT'S OPTION. If the price of a drug *or biological product* to a patient is lower than the amount of the patient's copayment under the patient's prescription drug insurance plan, the pharmacist shall offer the patient the option of paying for the drug *or biological product* at the lower price instead of paying the amount of the copayment.

SECTION 4. Section 562.005, Occupations Code, is amended to read as follows:

Sec. 562.005. RECORD OF DISPENSED DRUG *OR BIOLOGICAL PRODUCT*. A pharmacist shall record on the prescription form the name, strength, and manufacturer or distributor of a drug *or biological product* dispensed as authorized by this subchapter.

SECTION 5. Subchapter A, Chapter 562, Occupations Code, is amended by adding

Section 562.0051 to read as follows:

Sec. 562.0051. COMMUNICATION REGARDING CERTAIN DISPENSED BIOLOGICAL PRODUCTS. (a) Not later than the third business day after the date of dispensing a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner the specific product provided to the patient, including the name of the product and the manufacturer or national drug code number.

(b) The communication must be conveyed by making an entry into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy benefit management system or a pharmacy record, which may include information submitted for the payment of claims, that a pharmacist reasonably concludes is electronically accessible by the prescribing practitioner. Otherwise, the pharmacist or the pharmacist's designee shall communicate the biological product dispensed to the prescribing practitioner, using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication is not required if:

(1) there is no interchangeable biological product approved by the United States Food and Drug Administration for the product prescribed; or

(2) a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(c) This section expires September 1, 2019.

SECTION 6. Section 562.006, Occupations Code, is amended to read as follows:

Sec. 562.006. LABEL. (a) Unless otherwise directed by the practitioner, the label on the dispensing container must indicate the actual drug *or biological product* dispensed, indicated by either:

(1) the brand name; or

(2) if there is not a brand name, the *drug's* generic name *or the name of the biological product*, the strength of the drug *or biological product*, and the name of the manufacturer or distributor of the drug *or biological product*.

(b) [~~(a-1)~~] In addition to the information required by Subsection (a), the label on the dispensing container of a drug *or biological product* dispensed by a Class A or Class E pharmacy must indicate:

(1) the name, address, and telephone number of the pharmacy;

(2) the date the prescription is dispensed;

(3) the name of the prescribing practitioner;

(4) the name of the patient or, if the drug *or biological product* was prescribed for an animal, the species of the animal and the name of the owner;

(5) instructions for use;

(6) the quantity dispensed;

(7) if the drug *or biological product* is dispensed in a container other than the manufacturer's original container, the date after which the prescription should not be used, determined according to criteria established by board rule based on standards in the United States Pharmacopeia–National Formulary; and

(8) any other information required by board rule.

(c) [~~(a-2)~~] The information required by Subsection *(b)(7)* [~~(a-1)(7)~~] may be recorded on any label affixed to the dispensing container.

(d) [~~(a-3)~~] Subsection *(b)* [~~(a-1)~~] does not apply to a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication.

(e) [~~(b)~~] If a drug *or biological product* has been selected other than the one prescribed, the pharmacist shall place on the container the words "Substituted for brand prescribed" or "Substituted for 'brand name'" where "brand name" is the name of the brand name drug *or biological product* prescribed.

(f) [~~(e)~~] The board shall adopt rules requiring the label on a dispensing container to be in plain language and printed in an easily readable font size for the consumer.

SECTION 7. Section 562.008, Occupations Code, is amended to read as follows:

Sec. 562.008. GENERIC EQUIVALENT *OR INTERCHANGEABLE BIOLOGICAL PRODUCT* AUTHORIZED. (a) If a practitioner certifies on the prescription form that a specific prescribed brand is medically necessary, the pharmacist shall dispense the drug *or biological product* as written by the practitioner. The certification must be made as required by the dispensing directive adopted under Section 562.015. This subchapter does not permit a pharmacist to substitute a generically equivalent drug *or interchangeable biological product* unless the substitution is made as provided by this subchapter.

(b) Except as otherwise provided by this subchapter, a pharmacist who receives a prescription for a drug *or biological product* for which there is one or more generic equivalents *or one or more interchangeable biological products* may dispense any of the generic equivalents *or interchangeable biological products*.

SECTION 8. The heading to Section 562.009, Occupations Code, is amended to read as follows:

Sec. 562.009. REQUIREMENTS CONCERNING SELECTION OF GENERICALLY EQUIVALENT DRUG *OR INTERCHANGEABLE BIOLOGICAL PRODUCT*.

SECTION 9. Sections 562.009(a), (b), (c), and (d), Occupations Code, are amended to read as follows:

(a) Before delivery of a prescription for a generically equivalent drug *or interchangeable biological product*, a pharmacist must personally, or through the pharmacist's agent or employee:

(1) inform the patient or the patient's agent that a less expensive generically equivalent drug *or interchangeable biological product* is available for the brand prescribed; and

(2) ask the patient or the patient's agent to choose between the generically equivalent drug *or interchangeable biological product* and the brand prescribed.

(b) A pharmacy is not required to comply with the provisions of Subsection (a):

(1) in the case of the refill of a prescription for which the pharmacy previously complied with Subsection (a) with respect to the same patient or patient's agent; or

(2) if the patient's physician or physician's agent advises the pharmacy that:

(A) the physician has informed the patient or the patient's agent that a less expensive generically equivalent drug *or interchangeable biological product* is available for the brand prescribed; and

(B) the patient or the patient's agent has chosen either the brand prescribed or the less expensive generically equivalent drug *or interchangeable biological product*.

(c) A pharmacy that supplies a prescription by mail is considered to have complied with the provisions of Subsection (a) if the pharmacy includes on the prescription order form completed by the patient or the patient's agent language that clearly and conspicuously:

(1) states that if a less expensive generically equivalent drug *or interchangeable biological product* is available for the brand prescribed, the patient or the patient's agent may choose between the generically equivalent drug *or interchangeable biological product* and the brand prescribed; and

(2) allows the patient or the patient's agent to indicate the choice *between* [~~of~~] the generically equivalent drug *or interchangeable biological product and* [~~or~~] the brand prescribed.

(d) If the patient or the patient's agent fails to indicate otherwise to a pharmacy on the prescription order form under Subsection (c), the pharmacy may dispense a generically equivalent drug *or interchangeable biological product*.

SECTION 10. Section 562.010, Occupations Code, is amended to read as follows:

Sec. 562.010. RESPONSIBILITY CONCERNING GENERICALLY EQUIVALENT DRUG *OR INTERCHANGEABLE BIOLOGICAL PRODUCT*; LIABILITY. (a) A pharmacist who selects a generically equivalent drug *or interchangeable biological product* to be dispensed under this subchapter assumes the same responsibility for selecting the generically equivalent drug *or interchangeable biological product* as the pharmacist does in filling a prescription for a drug prescribed by generic *or biological product* name.

(b) The prescribing practitioner is not liable for a pharmacist's act or omission in selecting, preparing, or dispensing a drug *or biological product* under this subchapter.

SECTION 11. Section 562.011, Occupations Code, is amended to read as follows:

Sec. 562.011. RESTRICTION ON SELECTION OF AND CHARGING FOR GENERICALLY EQUIVALENT DRUG *OR INTERCHANGEABLE BIOLOGICAL PRODUCT*. (a) A pharmacist may not select a generically equivalent drug *or interchangeable biological product* unless the generically equivalent drug *or interchangeable biological product* selected costs the patient less than the prescribed drug *or biological product*.

(b) A pharmacist may not charge for dispensing a generically equivalent drug *or interchangeable biological product* a professional fee higher than the fee the pharmacist customarily charges for dispensing the brand name drug *or biological product* prescribed.

SECTION 12. Section 562.013, Occupations Code, is amended to read as follows:

Sec. 562.013. APPLICABILITY OF SUBCHAPTER. Unless a drug is determined to be generically equivalent to*, or a biological product is determined to be interchangeable with,* the brand prescribed, drug *or biological product* selection as authorized by this subchapter does not apply to:

(1) an enteric-coated tablet;

(2) a controlled release product;

(3) an injectable suspension, other than an antibiotic;

(4) a suppository containing active ingredients for which systemic absorption is necessary for therapeutic activity; or

(5) a different delivery system for aerosol or nebulizer drugs.

SECTION 13. Section 562.015(a), Occupations Code, is amended to read as follows:

(a) The board shall adopt rules to provide a dispensing directive to instruct pharmacists on the manner in which to dispense a drug *or biological product* according to the contents of a prescription. The rules adopted under this section must:

(1) require the use of the phrase "brand necessary" or "brand medically necessary" on a prescription form to prohibit the substitution of a generically equivalent drug *or interchangeable biological product* for a brand name drug *or biological product*;

(2) be in a format that protects confidentiality as required by the Health Insurance Portability and Accountability Act of 1996 *(Pub. L. No. 104-191)* [~~(29 U.S.C. Section 1181 et seq.)~~] and its subsequent amendments;

(3) comply with federal and state law, including rules, with regard to formatting and security requirements;

(4) be developed to coordinate with 42 C.F.R. Section *447.512* [~~447.331(c)~~]; and

(5) include an exemption for electronic prescriptions as provided by Subsection (b).

SECTION 14. Subchapter A, Chapter 562, Occupations Code, is amended by adding Section 562.016 to read as follows:

Sec. 562.016. LIST OF APPROVED INTERCHANGEABLE BIOLOGICAL PRODUCTS. The board shall maintain on the board's Internet website a link to the United States Food and Drug Administration's list of approved interchangeable biological products.

SECTION 15. (a) Chapter 562, Occupations Code, as amended by this Act, applies only to a prescription issued for a biological product on or after December 1, 2015. A prescription issued for a biological product before December 1, 2015, is governed by the law

in effect immediately before that date, and the former law is continued in effect for that purpose.

(b) The Texas State Board of Pharmacy shall adopt rules necessary to implement the changes in law made by this Act not later than December 1, 2015.

SECTION 16. This Act takes effect September 1, 2015.

Passed by the House on April 14, 2015: Yeas 146, Nays 0, 1 present, not voting; the House refused to concur in Senate amendments to H.B. No. 751 on May 8, 2015, and requested the appointment of a conference committee to consider the differences between the two houses; the House adopted the conference committee report on H.B. No. 751 on May 21, 2015: Yeas 144, Nays 0, 1 present, not voting; passed by the Senate, with amendments, on May 6, 2015: Yeas 31, Nays 0; at the request of the House, the Senate appointed a conference committee to consider the differences between the two houses; the Senate adopted the conference committee report on H.B. No. 751 on May 29, 2015: Yeas 31, Nays 0.

Approved June 19, 2015.

Effective September 1, 2015.

CAREGIVER SCREENING AND TRAINING BY SUBSTITUTE CARE PROVIDERS FOR CHILDREN IN THE CONSERVATORSHIP OF THE DEPARTMENT OF FAMILY AND PROTECTIVE SERVICES

CHAPTER 1008

H.B. No. 781

AN ACT

relating to caregiver screening and training by substitute care providers for children in the conservatorship of the Department of Family and Protective Services.

Be it enacted by the Legislature of the State of Texas:

SECTION 1. Section 40.058, Human Resources Code, is amended by adding Subsections (f), (g), and (h) to read as follows:

(f) A contract for residential child-care services provided by a general residential operation or by a child-placing agency must include provisions that:

(1) enable the department to monitor the effectiveness of the services;

(2) specify performance outcomes;

(3) authorize the department to terminate the contract or impose sanctions for a violation of a provision of the contract that specifies performance criteria;

(4) authorize the department, an agent of the department, and the state auditor to inspect all books, records, and files maintained by a contractor relating to the contract; and

(5) are necessary, as determined by the department, to ensure accountability for the delivery of services and for the expenditure of public funds.

(g) A contract with a private agency for the provision of substitute care or case management services for a child must include provisions that require the agency to provide access to the agency's information and records relating to the child to the child's attorney ad litem and guardian ad litem.

(h) In contracting with licensed child-placing agencies for residential child-care services, the department shall:

(1) determine and evaluate, using best practice standards, the home screening, as-